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Total Number of Pages in This Submission	57

Application Number	08/441,443
Filing Date	May 15, 1995
First Named Inventor	Michael HOUGHTON
Art Unit	1631
Examiner Name	M. Zeman
Attorney Docket Number	223002006316

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form
- [ ] Fee Attached
- [x] Amendment/Reply (53 pages)
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
- [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [x] Petition (2 pages)
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [x] Terminal Disclaimer (1 page)
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- [ ] Landscape Table on CD
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- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP (Customer No. 20872)		
Signature	/Otis Littlefield/		
Printed name	Otis Littlefield		
Date	October 26, 2007	Reg. No.	48,751

PTO/SB/64 (10-07)
Approved for use through 10/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)	Docket Number (Optional) 223002006316

First named inventor: Michael HOUGHTON

Application No: 08/441,443 Art Unit: 1631

Filed: May 15, 1995 Examiner: M. Zeman

Title: **NANBV DIAGNOSTICS AND VACCINES**

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee – required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. Petition fee

☐ Small entity – fee $ _____ (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.

☒ Other than small entity – fee $ 1,540.00 (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of _____ (identify type of reply):

☐ has been filed previously on _____ .

☒ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of $ _____ .

☐ has been paid previously on _____ .

☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☐ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☒ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____ for a small entity or $ 130.00 for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE. The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

/Otis Littlefield/	October 26, 2007
Signature	Date
Otis Littlefield	48,751
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MORRISON & FOERSTER LLP 425 Market Street San Francisco, California 94105-2482	(415) 268-6846
Address	Telephone Number

Enclosures:
- ☒ Fee Payment
- ☒ Reply (53 pages)
- ☒ Terminal Disclaimer Form (1 page)
- ☐ Additional sheets containing statements establishing unintentional delay
- ☐ Other: _____

Docket No.: 223002006316
Client Reference No.: PP00063.024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michael HOUGHTON et al.

Application No.: 08/441,443 Confirmation No.: 1917

Filed: May 15, 1995 Art Unit: 1631

For: NANBV DIAGNOSTICS AND VACCINES Examiner: M. Zeman

RESPONSE AFTER FINAL OFFICE ACTION (37 C.F.R. § 1.116)

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the final Office Action dated January 13, 2006 (Paper No. 20060106), for which a response was due on July 13, 2006. In response to this same final Office Action dated January 13, 2006, a Notice of Appeal and reply was timely filed on July 13, 2006. Applicants filed a Request for Continued Examination (RCE), along with a five-months extension of time, on February 13, 2007. Applicants respectfully request that this RCE be rescinded.

Moreover, this response addresses rejections in the non-final Office Action dated April 26, 2007 (Paper No. 20070423). In addition, this response is being submitted with a Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b) (Petition). Upon grant of the Petition, this response will be timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 39 of this paper.

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims:

Claims 1-59 (Canceled)

Claim 60 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 61 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 62 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of the viral cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 63 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of the viral cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 64 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 14, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 65 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 14, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 66 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 26, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 67 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 26, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 68 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figures 57, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 69 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 57, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 70 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 59 or the nucleotide sequence shown in Figure 62 or the complement thereof, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 71 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 59 or the nucleotide sequence shown in Figure 62 or the complement thereof, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claim 72 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 72 or the nucleotide sequence shown in Figure 89 or the complement thereof, wherein said polynucleotide has a maximum length of 353 nucleotides.

Claim 73 (Previously Presented): A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figure 72 or the nucleotide sequence shown in Figure 89 or the complement thereof, wherein said polynucleotide has a maximum length of 586 nucleotides.

Claims 74-75 (Canceled)

Claim 76 (Previously Presented): A polynucleotide according to any one of claims 60-73, wherein said contiguous sequence is at least 15 nucleotides.

Claim 77 (Previously Presented): A polynucleotide according to any one of claims 60-73, wherein said contiguous sequence is at least 20 nucleotides.

Claim 78 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide has a maximum length of 161 nucleotides.

Claims 79-80 (Canceled)

Claim 81 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide has a maximum length of 161 nucleotides.

Claim 82 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide has a maximum length of 161 nucleotides.

Claim 83 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide has a maximum length of 108 nucleotides.

Claims 84-85 (Canceled)

Claim 86 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide has a maximum length of 108 nucleotides.

Claim 87 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide has a maximum length of 108 nucleotides

Claim 88 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide is single stranded.

Claims 89-90 (Canceled)

Claim 91 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide is single stranded.

Claim 92 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide is single stranded.

Claim 93 (Previously Presented): A polynucleotide according to claim 78 wherein said polynucleotide is single stranded.

Claims 94-95 (Canceled)

Claim 96 (Previously Presented): A polynucleotide according to claim 81 wherein said polynucleotide is single stranded.

Claim 97 (Previously Presented): A polynucleotide according to claim 82 wherein said polynucleotide is single stranded.

Claim 98 (Previously Presented): A polynucleotide according to claim 83 wherein said polynucleotide is single stranded.

Claims 99-100 (Canceled)

Claim 101 (Previously Presented): A polynucleotide according to claim 86 wherein said polynucleotide is single stranded.

Claim 102 (Previously Presented): A polynucleotide according to claim 87 wherein said polynucleotide is single stranded.

Claim 103 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide is DNA.

Claims 104-105 (Canceled)

Claim 106 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide is DNA.

Claim 107 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide is DNA.

Claim 108 (Previously Presented): A polynucleotide according to claim 78 wherein said polynucleotide is DNA.

Claims 109-110 (Canceled)

Claim 111 (Previously Presented): A polynucleotide according to claim 81 wherein said polynucleotide is DNA.

Claim 112 (Previously Presented): A polynucleotide according to claim 82 wherein said polynucleotide is DNA.

Claim 113 (Previously Presented): A polynucleotide according to claim 83 wherein said polynucleotide is DNA.

Claims 114-115 (Canceled)

Claim 116 (Previously Presented): A polynucleotide according to claim 86 wherein said polynucleotide is DNA.

Claim 117 (Previously Presented): A polynucleotide according to claim 87 wherein said polynucleotide is DNA.

Claim 118 (Previously Presented): A polynucleotide according to claim 88 wherein said polynucleotide is DNA.

Claims 119-120 (Canceled)

Claim 121 (Previously Presented): A polynucleotide according to claim 91 wherein said polynucleotide is DNA.

Claim 122 (Previously Presented): A polynucleotide according to claim 92 wherein said polynucleotide is DNA.

Claim 123 (Previously Presented): A polynucleotide according to claim 93 wherein said polynucleotide is DNA.

Claims 124-125 (Canceled)

Claim 126 (Previously Presented): A polynucleotide according to claim 96 wherein said polynucleotide is DNA.

Claim 127 (Previously Presented): A polynucleotide according to claim 97 wherein said polynucleotide is DNA.

Claim 128 (Previously Presented): A polynucleotide according to claim 98 wherein said polynucleotide is DNA.

Claims 129-130 (Canceled)

Claim 131 (Previously Presented): A polynucleotide according to claim 101 wherein said polynucleotide is DNA.

Claim 132 (Previously Presented): A polynucleotide according to claim 102 wherein said polynucleotide is DNA.

Claim 133 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide is labeled.

Claims 134-135 (Canceled)

Claim 136 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide is labeled.

Claim 137 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide is labeled.

Claim 138 (Previously Presented): A polynucleotide according to claim 78 wherein said polynucleotide is labeled.

Claims 139-140 (Canceled)

Claim 141 (Previously Presented): A polynucleotide according to claim 81 wherein said polynucleotide is labeled.

Claim 142 (Previously Presented): A polynucleotide according to claim 82 wherein said polynucleotide is labeled.

Claim 143 (Previously Presented): A polynucleotide according to claim 83 wherein said polynucleotide is labeled.

Claims 144-145 (Canceled)

Claim 146 (Previously Presented): A polynucleotide according to claim 86 wherein said polynucleotide is labeled.

Claim 147 (Previously Presented): A polynucleotide according to claim 87 wherein said polynucleotide is labeled.

Claim 148 (Previously Presented): A polynucleotide according to claim 88 wherein said polynucleotide is labeled.

Claims 149-150 (Canceled)

Claim 151 (Previously Presented): A polynucleotide according to claim 91 wherein said polynucleotide is labeled.

Claim 152 (Previously Presented): A polynucleotide according to claim 92 wherein said polynucleotide is labeled.

Claim 153 (Previously Presented): A polynucleotide according to claim 93 wherein said polynucleotide is labeled.

Claims 154-155 (Canceled)

Claim 156 (Previously Presented): A polynucleotide according to claim 96 wherein said polynucleotide is labeled.

Claim 157 (Previously Presented): A polynucleotide according to claim 97 wherein said polynucleotide is labeled.

Claim 158 (Previously Presented): A polynucleotide according to claim 98 wherein said polynucleotide is labeled.

Claims 159-160 (Canceled)

Claim 161 (Previously Presented): A polynucleotide according to claim 101 wherein said polynucleotide is labeled.

Claim 162 (Previously Presented): A polynucleotide according to claim 102 wherein said polynucleotide is labeled.

Claim 163 (Previously Presented): A polynucleotide according to claim 103 wherein said polynucleotide is labeled.

Claims 164-165 (Canceled)

Claim 166 (Previously Presented): A polynucleotide according to claim 106 wherein said polynucleotide is labeled.

Claim 167 (Previously Presented): A polynucleotide according to claim 107 wherein said polynucleotide is labeled.

Claim 168 (Previously Presented): A polynucleotide according to claim 108 wherein said polynucleotide is labeled.

Claims 169-170 (Canceled)

Claim 171 (Previously Presented): A polynucleotide according to claim 111 wherein said polynucleotide is labeled.

Claim 172 (Previously Presented): A polynucleotide according to claim 112 wherein said polynucleotide is labeled.

Claim 173 (Previously Presented): A polynucleotide according to claim 113 wherein said polynucleotide is labeled.

Claims 174-175 (Canceled)

Claim 176 (Previously Presented): A polynucleotide according to claim 116 wherein said polynucleotide is labeled.

Claim 177 (Previously Presented): A polynucleotide according to claim 117 wherein said polynucleotide is labeled.

Claim 178 (Previously Presented): A polynucleotide according to claim 118 wherein said polynucleotide is labeled.

Claims 179-180 (Canceled)

Claim 181 (Previously Presented): A polynucleotide according to claim 121 wherein said polynucleotide is labeled.

Claim 182 (Previously Presented): A polynucleotide according to claim 122 wherein said polynucleotide is labeled.

Claim 183 (Previously Presented): A polynucleotide according to claim 123 wherein said polynucleotide is labeled.

Claims 184-185 (Canceled)

Claim 186 (Previously Presented): A polynucleotide according to claim 126 wherein said polynucleotide is labeled.

Claim 187 (Previously Presented): A polynucleotide according to claim 127 wherein said polynucleotide is labeled.

Claim 188 (Previously Presented): A polynucleotide according to claim 128 wherein said polynucleotide is labeled.

Claims 189-190 (Canceled)

Claim 191 (Previously Presented): A polynucleotide according to claim 131 wherein said polynucleotide is labeled.

Claim 192 (Previously Presented): A polynucleotide according to claim 132 wherein said polynucleotide is labeled.

Claim 193 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide is RNA.

Claims 194-195 (Canceled)

Claim 196 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide is RNA.

Claim 197 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide is RNA.

Claim 198 (Previously Presented): A polynucleotide according to claim 78 wherein said polynucleotide is RNA.

Claims 199-200 (Canceled)

Claim 201 (Previously Presented): A polynucleotide according to claim 81 wherein said polynucleotide is RNA.

Claim 202 (Previously Presented): A polynucleotide according to claim 82 wherein said polynucleotide is RNA.

Claim 203 (Previously Presented): A polynucleotide according to claim 83 wherein said polynucleotide is RNA.

Claims 204-205 (Canceled)

Claim 206 (Previously Presented): A polynucleotide according to claim 86 wherein said polynucleotide is RNA.

Claim 207 (Previously Presented): A polynucleotide according to claim 87 wherein said polynucleotide is RNA.

Claim 208 (Previously Presented): A polynucleotide according to claim 88 wherein said polynucleotide is RNA.

Claims 209-210 (Canceled)

Claim 211 (Previously Presented): A polynucleotide according to claim 91 wherein said polynucleotide is RNA.

Claim 212 (Previously Presented): A polynucleotide according to claim 92 wherein said polynucleotide is RNA.

Claim 213 (Previously Presented): A polynucleotide according to claim 93 wherein said polynucleotide is RNA.

Claims 214-215 (Canceled)

Claim 216 (Previously Presented): A polynucleotide according to claim 96 wherein said polynucleotide is RNA.

Claim 217 (Previously Presented): A polynucleotide according to claim 97 wherein said polynucleotide is RNA.

Claim 218 (Previously Presented): A polynucleotide according to claim 98 wherein said polynucleotide is RNA.

Claims 219-220 (Canceled)

Claim 221 (Previously Presented): A polynucleotide according to claim 101 wherein said polynucleotide is RNA.

Claim 222 (Previously Presented): A polynucleotide according to claim 102 wherein said polynucleotide is RNA.

Claim 223 (Previously Presented): A polynucleotide according to claim 193 wherein said polynucleotide is labeled.

Claims 224-225 (Canceled)

Claim 226 (Previously Presented): A polynucleotide according to claim 196 wherein said polynucleotide is labeled.

Claim 227 (Previously Presented): A polynucleotide according to claim 197 wherein said polynucleotide is labeled.

Claim 228 (Previously Presented): A polynucleotide according to claim 198 wherein said polynucleotide is labeled.

Claims 229-230 (Canceled)

Claim 231 (Previously Presented): A polynucleotide according to claim 201 wherein said polynucleotide is labeled.

Claim 232 (Previously Presented): A polynucleotide according to claim 202 wherein said polynucleotide is labeled.

Claim 233 (Previously Presented): A polynucleotide according to claim 203 wherein said polynucleotide is labeled.

Claims 234-235 (Canceled)

Claim 236 (Previously Presented): A polynucleotide according to claim 206 wherein said polynucleotide is labeled.

Claim 237 (Previously Presented): A polynucleotide according to claim 207 wherein said polynucleotide is labeled.

Claim 238 (Previously Presented): A polynucleotide according to claim 208 wherein said polynucleotide is labeled.

Claims 239-240 (Canceled)

Claim 241 (Previously Presented): A polynucleotide according to claim 211 wherein said polynucleotide is labeled.

Claim 242 (Previously Presented): A polynucleotide according to claim 212 wherein said polynucleotide is labeled.

Claim 243 (Previously Presented): A polynucleotide according to claim 213 wherein said polynucleotide is labeled.

Claims 244-245 (Canceled)

Claim 246 (Previously Presented): A polynucleotide according to claim 216 wherein said polynucleotide is labeled.

Claim 247 (Previously Presented): A polynucleotide according to claim 217 wherein said polynucleotide is labeled.

Claim 248 (Previously Presented): A polynucleotide according to claim 218 wherein said polynucleotide is labeled.

Claims 249-250 (Canceled)

Claim 251 (Previously Presented): A polynucleotide according to claim 221 wherein said polynucleotide is labeled.

Claim 252 (Previously Presented): A polynucleotide according to any of claims 60-73 wherein said polynucleotide is an oligonucleotide.

Claims 253-254 (Canceled)

Claim 255 (Previously Presented): A polynucleotide according to claim 76 wherein said polynucleotide is an oligonucleotide.

Claim 256 (Previously Presented): A polynucleotide according to claim 77 wherein said polynucleotide is an oligonucleotide.

Claim 257 (Previously Presented): A polynucleotide according to claim 78 wherein said polynucleotide is an oligonucleotide.

Claims 258-259 (Canceled)

Claim 260 (Previously Presented): A polynucleotide according to claim 81 wherein said polynucleotide is an oligonucleotide.

Claim 261 (Previously Presented): A polynucleotide according to claim 82 wherein said polynucleotide is an oligonucleotide.

Claim 262 (Previously Presented): A polynucleotide according to claim 83 wherein said polynucleotide is an oligonucleotide.

Claims 263-264 (Canceled)

Claim 265 (Previously Presented): A polynucleotide according to claim 86 wherein said polynucleotide is an oligonucleotide.

Claim 266 (Previously Presented): A polynucleotide according to claim 87 wherein said polynucleotide is an oligonucleotide.

Claim 267 (Previously Presented): A polynucleotide according to claim 222 wherein said polynucleotide is labeled.

Claim 268 (Previously Presented): An oligonucleotide according to claim 252 wherein said oligonucleotide is labeled.

Claims 269-270 (Canceled)

Claim 271 (Previously Presented): An oligonucleotide according to claim 255 wherein said oligonucleotide is labeled.

Claim 272 (Previously Presented): An oligonucleotide according to claim 256 wherein said oligonucleotide is labeled.

Claim 273 (Previously Presented): An oligonucleotide according to claim 257 wherein said oligonucleotide is labeled.

Claims 274-275 (Canceled)

Claim 276 (Previously Presented): An oligonucleotide according to claim 260 wherein said oligonucleotide is labeled.

Claim 277 (Previously Presented): An oligonucleotide according to claim 261 wherein said oligonucleotide is labeled.

Claim 278 (Previously Presented): An oligonucleotide according to claim 262 wherein said oligonucleotide is labeled.

Claims 279-280 (Canceled)

Claim 281 (Previously Presented): An oligonucleotide according to claim 265 wherein said oligonucleotide is labeled.

Claim 282 (Previously Presented): An oligonucleotide according to claim 266 wherein said oligonucleotide is labeled.

Claim 283 (Previously Presented): A polynucleotide according to claim 267 wherein said polynucleotide is an oligonucleotide.

Claim 284 (Previously Presented): A composition comprising the polynucleotide of any of claims 60-73 wherein said polynucleotide is substantially isolated.

Claims 285-286 (Canceled)

Claim 287 (Previously Presented): A composition comprising the polynucleotide of claim 76 wherein said polynucleotide is substantially isolated.

Claim 288 (Previously Presented): A composition comprising the polynucleotide of claim 77 wherein said polynucleotide is substantially isolated.

Claim 289 (Previously Presented): A composition comprising the polynucleotide of claim 78 wherein said polynucleotide is substantially isolated.

Claims 290-291 (Canceled)

Claim 292 (Previously Presented): A composition comprising the polynucleotide of claim 81 wherein said polynucleotide is substantially isolated.

Claim 293 (Previously Presented): A composition comprising the polynucleotide of claim 82 wherein said polynucleotide is substantially isolated.

Claim 294 (Previously Presented): A composition comprising the polynucleotide of claim 83 wherein said polynucleotide is substantially isolated.

Claims 295-296 (Canceled)

Claim 297 (Previously Presented): A composition comprising the polynucleotide of claim 86 wherein said polynucleotide is substantially isolated.

Claim 298 (Previously Presented): A composition comprising the polynucleotide of claim 87 wherein said polynucleotide is substantially isolated.

Claim 299 (Previously Presented): A composition comprising the polynucleotide of claim 88 wherein said polynucleotide is substantially isolated.

Claims 300-301 (Canceled)

Claim 302 (Previously Presented): A composition comprising the polynucleotide of claim 91 wherein said polynucleotide is substantially isolated.

Claim 303 (Previously Presented): A composition comprising the polynucleotide of claim 92 wherein said polynucleotide is substantially isolated.

Claim 304 (Previously Presented): A composition comprising the polynucleotide of claim 93 wherein said polynucleotide is substantially isolated.

Claims 305-306 (Canceled)

Claim 307 (Previously Presented): A composition comprising the polynucleotide of claim 96 wherein said polynucleotide is substantially isolated.

Claim 308 (Previously Presented): A composition comprising the polynucleotide of claim 97 wherein said polynucleotide is substantially isolated.

Claim 309 (Previously Presented): A composition comprising the polynucleotide of claim 98 wherein said polynucleotide is substantially isolated.

Claims 310-311 (Canceled)

Claim 312 (Previously Presented): A composition comprising the polynucleotide of claim 101 wherein said polynucleotide is substantially isolated.

Claim 313 (Previously Presented): A composition comprising the polynucleotide of claim 102 wherein said polynucleotide is substantially isolated.

Claim 314 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of any of claims 60-73 in a suitable package.

Claims 315-316 (Canceled)

Claim 317 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 76 in a suitable package.

Claim 318 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 77 in a suitable package.

Claim 319 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 78 in a suitable package.

Claims 320-321 (Canceled)

Claim 322 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 81 in a suitable package.

Claim 323 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 82 in a suitable package.

Claim 324 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 83 in a suitable package.

Claims 325-326 (Canceled)

Claim 327 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 86 in a suitable package.

Claim 328 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 87 in a suitable package.

Claim 329 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 88 in a suitable package.

Claims 330-331 (Canceled)

Claim 332 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 113 in a suitable package.

Claim 333 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 117 in a suitable package.

Claim 334 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 133 in a suitable package.

Claim 335 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 193 in a suitable package.

Claim 336 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 223 in a suitable package.

Claim 337 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 252 in a suitable package.

Claim 338 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 284 in a suitable package.

Claim 339 (Previously Presented): A kit for analyzing samples for the presence of HCV comprising at least one polynucleotide of claim 268 in a suitable package.

Claim 340 (Previously Presented): A polynucleotide of any of claims 60-73 wherein said polynucleotide encodes a polypeptide having a sequence comprising at least 10 contiguous amino acids from an HCV1 polyprotein.

Claim 341 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 3.

Claim 342 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 62A.

Claim 343 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 89.

Claim 344 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

Claim 345 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-ll cDNA library deposited as ATCC No. 40394.

Claim 346 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 89.

Claim 347 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 14.

Claim 348 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of Figure 58.

Claim 349 (Previously Presented): A method according to any of claims 344-348 wherein said selected samples comprise said polynucleotide and said stringent conditions permit the formation of a stable hybrid duplex between said polynucleotide and said contiguous sequence and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

Claim 350 (Canceled)

Claim 351 (Previously Presented): A method according to claim 349 wherein said polynucleotide is detectable in a PCR assay.

Claim 352 (Previously Presented): A method according to claim 349 wherein said biological samples are blood.

Claim 353 (Canceled)

Claim 354 (Previously Presented): A method according to claim 351 wherein said biological samples are blood.

Claim 355 (Previously Presented): A method according to claim 349 wherein said biological samples are plasma.

Claim 356 (Canceled)

Claim 357 (Previously Presented): A method according to claim 351 wherein said biological samples are plasma.

Claim 358 (Previously Presented): A method according to claim 349 wherein said biological samples are sera.

Claim 359 (Canceled)

Claim 360 (Previously Presented): A method according to claim 351 wherein said biological samples are sera.

Claim 361 (Previously Presented): A method according to claim 352 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 362 (Previously Presented): A method according to claim 355 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 363 (Previously Presented): A method according to claim 352 further comprising preparing polyclonal antibodies with selected biological samples.

Claim 364 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

Claim 365 (Previously Presented): A method of selecting biological samples from a supply of human biological samples comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt- 11 cDNA library deposited as ATCC No. 40394.

Claim 366 (Previously Presented): A method according to claim 352 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 367 (Canceled)

Claim 368 (Previously Presented): A method according to claim 354 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 369 (Previously Presented): A method according to claim 355 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 370 (Canceled)

Claim 371 (Previously Presented): A method according to claim 357 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 372 (Previously Presented): A method according to claim 358 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 373 (Canceled)

Claim 374 (Previously Presented): A method according to claim 360 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 375 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

Claim 376 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which do not comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second

polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

Claim 377 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-ll cDNA library deposited as ATCC No. 40394.

Claim 378 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which do not comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-ll cDNA library deposited as ATCC No. 40394.

Claim 379 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides found in Figure 89, or the complement thereof.

Claim 380 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which do not comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides found in Figure 89, or the complement thereof.

Claim 381 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which comprise a first

polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides found in either strand of Figure 58.

Claim 382 (Previously Presented): A method of selecting samples from a supply of human biological samples comprising selecting from said supply those samples which do not comprise a first polynucleotide that is capable of hybridizing under stringent conditions to a second polynucleotide that comprises a contiguous sequence of at least 15 nucleotides found in either stand of Figure 58.

Claim 383 (Previously Presented): A method according to any of claims 375, 377, 379, 381 wherein said selected samples comprise said first polynucleotide and said stringent conditions permit the formation of a stable hybrid duplex between said first polynucleotide and said contiguous sequence of nucleotides and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

Claim 384 (Previously Presented): A method according to any of claims 376, 378, 380, 382 wherein said selected samples do not comprise said first polynucleotide and said stringent conditions permit the formation of a stable hybrid duplex between said first polynucleotide and said contiguous sequence and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

Claim 385 (Previously Presented): A method according to claim 383, wherein said stringent conditions include using 50% (w/v) formamide and washing in 5xSSC, 0.1 % SDS at 55 DC.

Claim 386 (Previously Presented): A method according to claim 384, wherein said stringent conditions include using 50% (w/v) formamide and washing in 5xSSC, 0.1 % SDS at 55 DC.

Claim 387 (Previously Presented): A method according to claim 383 wherein said first polynucleotide is detectable in a PCR assay.

Claim 388 (Previously Presented): A method according to 385, wherein said first polynucleotide is detectable in a PCR assay.

Claim 389 (Previously Presented): A method according to claim 384 wherein said first polynucleotide is not detectable in a PCR assay.

Claim 390 (Previously Presented): A method according to claim 386 wherein said first polynucleotide is not detectable in a PCR assay.

Claim 391 (Previously Presented): A method according to any of claims 375-382 wherein said biological samples are blood.

Claim 392 (Previously Presented): A method according to claim 383 wherein said biological samples are blood.

Claim 393 (Previously Presented): A method according to claim 384 wherein said biological samples are blood.

Claim 394 (Previously Presented): A method according to claim 385 wherein said biological samples are blood.

Claim 395 (Previously Presented): A method according to claim 386 wherein said biological samples are blood.

Claim 396 (Previously Presented): A method according to claim 387 wherein said biological samples are blood.

Claim 397 (Previously Presented): A method according to claim 388 wherein said biological samples are blood.

Claim 398 (Previously Presented): A method according to claim 389 wherein said biological samples are blood.

Claim 399 (Previously Presented): A method according to claim 390 wherein said biological samples are blood.

Claim 400 (Previously Presented): A method according to any of claims 375-382 wherein said biological samples are plasma.

Claim 401 (Previously Presented): A method according to claim 383 wherein said biological samples are plasma.

Claim 402 (Previously Presented): A method according to claim 384 wherein said biological samples are plasma.

Claim 403 (Previously Presented): A method according to claim 385 wherein said biological samples are plasma.

Claim 404 (Previously Presented): A method according to claim 386 wherein said biological samples are plasma.

Claim 405 (Previously Presented): A method according to claim 387 wherein said biological samples are plasma.

Claim 406 (Previously Presented): A method according to claim 388 wherein said biological samples are plasma.

Claim 407 (Previously Presented): A method according to claim 389 wherein said biological samples are plasma.

Claim 408 (Previously Presented): A method according to claim 390 wherein said biological samples are plasma.

Claim 409 (Previously Presented): A method according to any of claims 375-382 wherein said biological samples are sera.

Claim 410 (Previously Presented): A method according to claim 383 wherein said biological samples are sera.

Claim 411 (Previously Presented): A method according to claim 384 wherein said biological samples are sera.

Claim 412 (Previously Presented): A method according to claim 385 wherein said biological samples are sera.

Claim 413 (Previously Presented): A method according to claim 386 wherein said biological samples are sera.

Claim 414 (Previously Presented): A method according to claim 387 wherein said biological samples are sera.

Claim 415 (Previously Presented): A method according to claim 388 wherein said biological samples are sera.

Claim 416 (Previously Presented): A method according to claim 389 wherein said biological samples are sera.

Claim 417 (Previously Presented): A method according to claim 390 wherein said biological samples are sera.

Claim 418 (Previously Presented): A method according to any of claims 375, 377, 379 or 381 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 419 (Previously Presented): A method according to claim 383 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 420 (Previously Presented): A method according to claim 385 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 421 (Previously Presented): A method according to claim 387 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 422 (Previously Presented): A method according to claim 388 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 423 (Previously Presented): A method according to any of claims 376, 378, 380 or 382 further comprising employing biological samples that are selected for a preparation of blood-related products.

Claim 424 (Previously Presented): A method according to claim 384 further comprising employing biological samples that are selected for a preparation of blood-related products.

Claim 425 (Previously Presented): A method according to claim 386 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 426 (Previously Presented): A method according to claim 389 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 427 (Previously Presented): A method according to claim 390 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 428 (Previously Presented): A method according to any of claims 376, 378, 380 or 382 wherein said selected samples are supply samples for preparation of blood products.

Claim 429 (Previously Presented): A method according to claim 384 wherein said selected samples are supply sample for preparation of blood products.

Claim 430 (Previously Presented): A method according to claim 386 wherein said selected samples are supply sample for preparation of blood products.

Claim 431 (Previously Presented): A method according to claim 389 wherein said selected samples are supply sample for preparation of blood products.

Claim 432 (Previously Presented): A method according to claim 390 wherein said selected samples are supply sample for preparation of blood products.

Claim 433 (Previously Presented): A method according to any of claims 375, 377, 379 or 381 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 434 (Previously Presented): A method according to claim 383 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 435 (Previously Presented): A method according to claim 385 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 436 (Previously Presented): A method according to claim 387 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 437 (Previously Presented): A method according to claim 388 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 438 (Previously Presented): A method according to any of claims 341-348, 364 or 365 wherein said polynucleotide is detectable in a PCR assay.

Claim 439 (Previously Presented): A method according to claim 438 wherein said biological samples are blood.

Claim 440 Previously Presented) : A method according to claim 438 wherein said biological samples are plasma.

Claim 441 (Previously Presented): A method according to claim 438 wherein said biological samples are sera.

Claim 442 (Previously Presented): A method according to claim 439 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 443 (Previously Presented): A method according to claim 440 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 444 (Previously Presented): A method according to claim 441 wherein the selecting is to identify an HCV positive sample for removal from the supply.

Claim 445 (Previously Presented): A method according to claims 344-348, wherein said stringent conditions include using 50% (w/v) formamide and washing in 5xSSC, 0.1 % SDS at 55 DC.

Claim 446 (Previously Presented): A method according to claim 349 wherein said stringent conditions include using 50% (w/v) formamide and washing in 5xSSC, 0.1 % SDS at 55 DC.

Claim 447 (Previously Presented): A method according to claim 445 wherein said polynucleotide is detectable in a PCR assay.

Claim 448 (Previously Presented): A method according to claim 446 wherein said polynucleotide is detectable in a PCR assay.

Claim 449 (Previously Presented): A method according to claim 445 wherein said biological samples are blood.

Claim 450 (Previously Presented): A method according to claim 446 wherein said biological samples are blood.

Claim 451 (Previously Presented): A method according to claim 445 wherein said biological samples are plasma.

Claim 452 (Previously Presented): A method according to claim 446 wherein said biological samples are plasma.

Claim 453 (Previously Presented): A method according to claim 445 wherein said biological samples are sera.

Claim 454 (Previously Presented): A method according to claim 446 wherein said biological samples are sera.

Claim 455 (Previously Presented): A method according to claim 447 wherein said biological samples are blood.

Claim 456 (Previously Presented): A method according to claim 448 wherein said biological samples are blood.

Claim 457 (Previously Presented): A method according to claim 447 wherein said biological samples are sera.

Claim 458 (Previously Presented): A method according to claim 448 wherein said biological samples are sera.

Claim 459 (Previously Presented): A method according to claim 447 wherein said biological samples are plasma.

Claim 460 (Previously Presented): A method according to claim 448 wherein said biological samples are plasma.

Claim 461 (Previously Presented): A method according to claim 445 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 462 (Previously Presented): A method according to claim 446 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 463 (Previously Presented): A method according to claim 447 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 464 (Previously Presented): A method according to claim 448 further comprising employing biological samples that are not selected for a preparation of blood-related products.

Claim 465 (Previously Presented): A method according to claim 445 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 466 (Previously Presented): A method according to claim 446 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 467 (Previously Presented): A method according to claim 447 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 468 (Previously Presented): A method according to claim 448 wherein said samples that are not selected are supply samples for preparation of blood products.

Claim 469 (Previously Presented): A method according to claim 358 further comprising employing biological samples that are not selected for a preparation of blood-related products.

REMARKS

As of the final Office Action issued January 13, 2006, claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, 332-340, 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are pending in the present application.

Claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected.

No new amendments or claims are included with this response. Reconsideration of the application and an Advisory Action is respectfully requested in view of the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the order in which they were raised in the Office Action.

A. Request to Rescind the Request for Continued Examination

Applicants respectfully request that upon grant of the petition to revive filed herewith, the Request for Continued Examination filed February 13, 2007 be rescinded.

B. Teleconference with Examiner M. Zeman

The applicants gratefully acknowledge and thank Examiner M. Zeman for the very helpful teleconference October 25, 2007. The applicants and Examiner M. Zeman discussed the filing of the Request for Continued Examination. The applicants and Examiner M. Zeman agreed that this response to the final Office Action dated January 13, 2006 would filed with a Petition to Revive and a request to rescind the Request for Continued Examination.

C. Allowable claims

Applicants appreciate the Examiner's determination that claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

D. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description.

Specifically the Examiner alleges that the Specification, as filed, lacks support for the claim limitation of at least 12 contiguous nucleotides but less than "some arbitrary length." (Office Action at 2-3). In a telephone interview with Applicants' representative, the Examiner noted her concern with alleged lack of support for the *genus* of "at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of XXX."

Applicants respectfully traverse. The minimum and maximum lengths recited in the claims are not arbitrary but are specific lengths of polynucleotide sequences disclosed in the Specification, which also provides written description support under 35 U.S.C. § 112, first paragraph for the claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of " 353, 586, 108 or 161 nucleotides as

recited in claims 60-73, 78, 81-83, 86 and 87. The remainder of the rejected claims stand rejected on the basis of their dependence from claims 60-73, 78, 81-83, 86 and 87.

A description of a genus of DNAs may be achieved by means of a recitation of a representative number of DNA sequences

Although the Federal Circuit has used various expressions to set forth the standards for compliance with *§ 112*, it is clear that the written description requirement does not require a patent applicant to provide a verbatim description of all his claims in the disclosure. *See Union Oil Co. Of Cal. v. Atl. Richfield Co ("UNOCAL"), 208 F.3d 989, 997-1001 (Fed. Cir. 2000).* Rather, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996); see also Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)*("The test for sufficiency of support in a patent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'")(citing *Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)).*

The written description requirement does not dictate that the applicant describe the invention exactly. Rather, what is required is that, as of the filing date, the inventor convey with reasonable clarity to those skilled in the art that the inventor was in possession of the subject matter claimed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). In order to comply with the written description requirement, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed." *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002) (citations omitted).

One shows that one is "in possession" of an invention by describing the invention with all its claimed limitations through "such descriptive means as words, structures, figures, diagrams,

formulas, etc., that fully set forth the claimed invention." *Hyatt v. Dudas 393 F. Supp. 2d 1 (D.C. Cir. 2005)* citing *Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).*

The Federal Circuit has addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)

(i) Claim term: *at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 353 nucleotides*

Claims 60, 62, 64, 66, 68, 70 and 71 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in ... whercin said polynucleotide has a maximum length of 353 nucleotides."

Applicants submit that while thc claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequencc of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 353 nucleotides" may not be explicitly recited in the Specification one of skill in the art would have understood that Applicants were in possession of the claimed invention from reviewing the Specification.[1]

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 353 nucleotides" is found in the Specification. The complete nucleotide sequence of a 353 nucleotides long clone 81 of HCV cDNA is shown in Figure 4 and described in the Specification in section IV.C.1. Its use as a probe for identifying RNA from liver by Northern hybridization is disclosed in the Specification at page 170, line 28 – page 171 , line 19.

Explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification.

Applicants note that the Examiner has identified support for term specifying a minimum length of polynucleotide: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-353 nucleotides.

A representative number of species encompassing the range of 12-353 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Given the complete nucleotide sequence of a 353 bp long polynucleotide and the specific disclosure of polynucleotides encompassing 12, 15, 16, 20, 30, 80, 108, and 161 long species within the 353 long sequence, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in ... wherein said polynucleotide has a maximum length of 353 nucleotides."

(ii) Claim term: *at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 108 nucleotides*

Claims 83, 86 and 87 specify: "[at least 12 contiguous nucleotides]... wherein said polynucleotide has a maximum length of 108 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequcnce of at least 12 contiguous nucleotides" is found in

[1] Applicants note that the claims are not limited to "probes" but to all polynucleotides encompassing at least 12 nucleotides of the specified sequence.

the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. The upper limit of a 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-108 nucleotides and a representative number of species encompassing the range of 12-108 nucleotides.

(iii) Claim term: *at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 161 nucleotides*

Claims 78, 81 and 82 specify: "[at least 12 contiguous nucleotides]... wherein said polynucleotide has a maximum length of 161 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. The upper limit of a 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-161 nucleotides and a representative number of species encompassing the range of 12-161 nucleotides.

(iv) Claim term: *at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides*

Claims 61, 63, 65, 67, 69, 71 and 73 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification.

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 586 nucleotides" is found in the Specification. HCV polynucleotides 586 nucleotides in length are disclosed in section IV.C.3 and specifically at page 176, lines 34-35 of the Specification. The preparation of the 586 nucleotides long polynucleotide is disclosed at page 175, line 7 – page 176, line 35.

The complete nucleotide sequence of the 586 nucleotide long polynucleotide can be obtained from aligning the clone 36 and clone 37b primers on page 175, lines 20 and 24 of the Specification with the sequence disclosed in Figures 5, 8 and 10 of overlapping clones 35, 36 and 37b.

A representative number of species encompassing the range of 12-586 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 also discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353

nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Nucleotide sequences of polynucleotides comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides, are also disclosed in relation to the 586 base polynucleotide at page 176, lines 18-24 and 34-35 of the Specification, in Figure 5 (a polynucleotide 406 nucleotides in length), Figure 8 (a polynucleotide 480 nucleotides in length), and Figure 10 (a polynucleotide 268 nucleotides in length).

Therefore, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: [a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figures 1, 3, 4, 14, 26, 57, 59, 62, 72, or the nucleotide sequence in any of the viral cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394, wherein said polynucleotide has a maximum length of 586 nucleotides.

Thus, the Specification provides an adequate description of a genus of HCV DNA sequences of at least 12 and up to 108, 161, 353 and 586 nucleotides in length by identifying DNA sequences at the lower and upper limits and a representative number of DNA sequences falling within the scope of the genus and constituting a substantial portion of the genus.

Claims 76-77, 88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 depend from claims 60-73, 78, 81-83, 86 and 87 whose written description support in the specification under 35 U.S.C. § 112, first paragraph is discussed above.

Therefore Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

E. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 were rejected under 35 U.S.C. § 112, first paragraph, in the Office Action issued April 26 2007, for alleged lack of written description. To advance prosecution, applicants respectfully traverse the rejection and its supporting remarks.

The Examiner rejected the pending claims for allegedly failing to satisfy the written description requirement in the Office Action dated April 26, 2007. The Examiner cites case authority regarding the requirements for claiming a genus when an application discloses only a single or a limited number of species. Applicants respectfully submit that the cases cited are not on point. In the instant application, all of the claimed subject matter is fully described in accordance with Section 112, rendering inapplicable case law directed to the requirements for an applicant to claim a broader genus based on a limited disclosure of species.

As an initial matter, the Examiner states that "The independent claims . . . each recite polynucleotides of at least 12 contiguous nucleotides, and less than some arbitrary length, in most cases the length of the nucleic acid in the associated Figure. The specification, as filed does not provide basis for this scope of these claims." However, applicants in their July 13, 2006 Response After Final Office Action (37 C.F.R. § 1.116) have cited specific support for the upper and lower limits for the claimed polynucleotides. As defined in the specification, "the term 'polynucleotide' ... refers to a polymeric form of nucleotides of any length." (Page 28, lines 19-20). Applicants in their July 13, 2006 Response cited to specific support for the 12 nucleotide lower limit, to specific polynucleotides supporting the upper limits (of 353, 108, 161, and 586 nucleotides), and to polynucleotides of lengths falling within the claimed limits. (July 13, 2006 Response at 39-45).

The Examiner further states that "The claims do not require that the polynucleotides are HCV specific." However, there is no requirement that the claims recite such a limitation. While the specification makes clear that the claimed polynucleotides have utility in, for example, detecting HCV in samples (*e.g.*, page 61, line 5 to page 64, line 2), there is no requirement in the patent laws that the utility of a claimed invention has to be recited in the claim. The Examiner also states that "There is no adequate link between structure and function for the polynucleotides encompassed by the pending claims." To the contrary, the specification plainly describes that the claimed polynucleotides can function as diagnostic oligonucleotides and probes specifically based on their structure (*i.e.*, their nucleotide sequence) and therefore can "hybridize with the HCV genome and are useful in identification of the viral agent(s), further characterization of the viral genome(s), as well as in detection of the virus(es) in diseased individuals." (Page 61, lines 9-13). Moreover, in the instant application, applicants have in fact described the structure of the claimed polynucleotides and are not relying on a description of function as a description of structure, even though such a description was held acceptable in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002), based on the PTO's Synopsis of Application of Written Description Guidelines. ("The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar," citing Example 9).

The present written description rejection is based on the incorrect premise that applicants are attempting to claim broad genuses of polynucleotides supported only by the description of a limited number of species. Thus, the Examiner states that "The specification provides basis for the specific HCV isolates sequenced and deposited under the recited deposit numbers. The specification does not provide for broad definitions of polynucleotides comprising at least 12 nucleotides and some amount of undisclosed sequences." In support of this rejection, the Examiner cites case law in which applicants have attempted to claim a broad genus based on the description of only a single or a limited number of species, such as in *Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-69 (Fed. Cir. 1997), involving claims to all vertebrate or mammalian insulin cDNA when the disclosure only described a single species, rat insulin cDNA.

However, the instant claims and disclosure are completely different from those at issue in *Eli Lilly* and the other cases relied upon by the Examiner.

Applicants claimed invention is based on their discovery of the viral agent which causes Non-A, Non-B Hepatitis, now known as Hepatitis C or HCV. Applicants' discovery of HCV and their determination of its nucleotide sequence allowed for the development of, among other things, powerful diagnostic tests for determining the presence or absence of HCV in biological samples. Among these diagnostic tests are nucleic acid tests based on the HCV nucleotide sequence discovered by applicants and fully described in their application. (See Section II. H. of the specification, beginning at page 61, line 4). Applicants' specification and Figures fully describe the HCV nucleotide sequence and how polynucleotides comprising nucleotides based on the HCV sequence can be used in, for example, detecting the presence of HCV in samples.

Thus, applicants' specification clearly shows that they are in possession of polynucleotides of at least 12 contiguous nucleotides that are set forth in the referenced Figures describing nucleotide sequence information for HCV. The Examiner's written description rejection seems to be based on whether the claims encompass polynucleotides that include, in addition to at least 12 nucleotides from the referenced Figures, other "undisclosed sequences" that are not in the Figures (and which therefore are not found in, or are not complementary, to HCV). However, the claims are open to the inclusion of such additional nucleotides and one skilled in the art would recognize and understand that any such additional nucleotides, whatever they may be, are irrelevant to applicants' invention and particular contribution to the art. The claimed polynucleotides are novel, non-obvious, useful, enabled, and described based on applicants' disclosure of the HCV nucleotide sequence. One skilled in the art reading applicants' specification would readily understand that applicants were in possession of the full range of the claims because any variability created by the possible inclusion of non-HCV nucleotides beyond the required "at least 12" is not relevant to the invention.

The instant claims are therefore analogous to Example 8 of the PTO's Synopsis of Application of Written Description Guidelines, Example 8 (entitled, "DNA fragment Encoding a Full Open Reading Frame (ORF)"). In that example, a claim to a nucleotide sequence (SEQ ID NO:

2), was stated to satisfy the written description requirement even though it was interpreted to cover "a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 2" while the specification only disclosed "a single species . . . (a molecule consisting of SEQ ID NO: 2 . . .)." The example states that the written description requirement is satisfied "[a]lthough there may be substantial variability among the species of DNAs encompassed with the scope of the claim because SEQ ID NO: 2 may be combined with sequences known in the art." The example concludes that "[w]eighing all the factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2." (Synopsis of Application of Written Description Guidelines at p. 34-35.). Here, applicants' contribution is the identification of the HCV sequence and oligonucleotides comprising 12 or more nucleotides from the referenced Figures setting forth HCV sequences. One skilled in the art would readily understand that any variability introduced by the possible inclusion of other nucleotides in addition to the 12 or more nucleotides from the referenced Figures "arises due to addition of elements that are not part of the inventor's particular contribution." One skilled in the art would recognize that because the specific identification of any such additional nucleotides is irrelevant, that the instant applicants were "in possession of the genus" of polynucleotides claimed.

Moreover, each rejected claim specifically recites polynucleotides found exactly in the nucleotide sequences of specific Figures referenced in the claims. For example, claim 60 recites:

> A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of 353 nucleotides.

One skilled in the art need only look to the referenced Figures for a description of each claimed polynucleotide. Each polynucleotide within the scope of the claim is thus described so that one skilled in the art knows based on the disclosure, including the referenced Figures, precisely what is covered by the claim. Indeed, there is nothing for one skilled in the art to do other than to

read the referenced Figures, and select polynucleotides comprising from 12 to 353 contiguous nucleotides exactly as described in the Figures. The same holds for each of applicants' additional claims reciting polynucleotides of specified lengths with reference to the application's Figures. The possible inclusion of additional nucleotides not found in the referenced Figures does not negate the description of the HCV sequences encompassed by the claimed polynucleotides. One skilled in the art reading applicants' specification and Figures would instantly understand that applicants described and were in possession of the claimed polynucleotides, even if the claims were open to inclusion of additional nucleotides. Unlike in the cases relied upon by the Examiner, there are no non-described species which the applicants seek to embrace within a broad genus based on a single or limited number of described species.

Thus, the instant claims and disclosure are entirely unlike those discussed in the cases cited by the Examiner. For example, this not a case like *Eli Lilly*, 119 F.3d at 1567-69, in which the inventors attempted to claim the entire genera of cDNA encoding vertebrate and mammalian insulin sequences based on the single disclosure of cDNA encoding rat insulin. Nor is it a case like *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004) in which an applicant attempted to "claim the genus form of CD40CR antibody by simply describing mouse CD40CR." Nor is it a case like *In re Curtis*, 354 F.3d 1347, 1349 (Fed. Cir. 2004) in which the applicant argued that the disclosure in a parent application of a single species of a microcrystalline wax coating for PTFE supported a claim to a "genus of friction enhancing coatings," as later described in a CIP application. Nor is it a case like *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004), in which an applicant attempted to claim a method of selectively inhibiting an activity by administering a class of compounds without describing even a single member of that class.

In contrast to these cases, each embodiment of the instant claims is fully described in the specification and Figures. One skilled in the art reading the claims need do no more than turn to the referenced Figures to determine the sequence of each claimed polynucleotide.

In discussing the case law, the Examiner stated "For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See e.g., Eli Lilly." As made clear above,

however, the instant invention does not present such a case. All the polynucleotides within the scope of each claim are expressly described with reference to the recited Figures. Applicants are not attempting to claim "widely variant species . . by disclosing only one species within the genus." This is not a case in which applicants are attempting to generalize in an "unpredictable art" from a limited disclosure of species. Each polynucleotide within the scope of the claims is described, leaving nothing to "prediction." Moreover, applicants' method claims (*e.g.*, claims 344 to 349) are based on the well-known and *predictable* ability of polynucleotides to hybridize to complementary sequences. See *Enzo Biochem*, 323 F.3d at 966 (discussing the nucleic acid hybridization example 9 of the PTO's Synopsis of Application of Written Description Guidelines).

Finally, applicants note that the Examiner states at pages 3-4 of the Office Action dated April 26, 2007, that:

> Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

This language, which is a direct quote from *In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004), demonstrates that the disclosure of a protein's amino acid sequence provides written description support for each nucleic acid sequence encoding that protein.[2] However, even such a sufficient disclosure provides far less written description support than applicants' instant disclosure which provides the actual nucleic acid sequence for each claimed polynucleotide. This is not a case where the issue is whether or not the applicants have disclosed "a representative number of adequately described species" to support a genus. Here, applicants have disclosed all claimed embodiments, not merely a representative number.

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[2] Applicants note that the two cases cited by the examiner, *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382 (Fed, Cir. 1994), relate to determinations by the Federal Circuit that the prior art disclosure of a very large genus did not render obvious a claim to a species falling within the genus. Thus, in *Bell*, the Federal Circuit reversed an obviousness rejection of a claim to the nucleic acid sequences of human IGF I and II over prior art disclosing the amino acid sequences of IGF I and II, and in *Baird*, the Federal Circuit reversed an obviousness rejection of a claim to a specific bisphenol A compound over a prior art reference disclosing a genus encompassing "more than

CONCLUSION

In view of the foregoing, applicants respectfully submit that the pending claims fully satisfy the written description requirement and respectfully request withdrawal of the outstanding rejection and allowance of the claims.

Finally, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to ***Deposit Account No. 03-1952*** referencing docket no. 223002006316. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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100 million different diphenols, only one of which is bisphenol A." Applicants respectfully submit that neither of these cases support the examiner's rejection based on written description.